



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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The Weinberg Group Inc.
Attention: Nicholas M. Fleischer, Ph.D.
1220 Nineteenth Street, NW, Suite 300
Washington, DC 20036-2400

Docket No. 2005P-0257/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on June 22, 2005, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Methylphenidate Hydrochloride Extended-release Tablets, 72 mg. The reference listed drug product to which you refer in your petition is Concerta (Methylphenidate Hydrochloride) Extended-release Tablets, 54 mg, approved under NDA 21-121 held by Alza Corporation. You note that Concerta is available in dosage strengths of 18 mg, 27 mg, 36 mg, and 54 mg.

Your request involves a change in strength from that of the listed drug product (i.e., from 54 mg to 72 mg). The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The FDA finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug product are the same as that of the listed drug product. In addition, the labeling for the reference listed drug references a dosage strength of 72 mg as the maximum daily dose for adolescents 13 to 17 years of age. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

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For your information, the listed drug product to which you refer is covered by periods of patent protection and exclusivity which appear in the Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book), published by the FDA. The existence of such patents and exclusivity will require patent certification and exclusivity statements upon submission of an ANDA for your proposed drug product and may also affect the approval date of any ANDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Gary Buehler", with a stylized flourish at the end.

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research